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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,905

04/30/2007

Kunihiro Hattori

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EXAMINER

OUSPENSKI, ILIA I

ART UNIT

PAPER NUMBER

1644

NOTIFICATION DATE

DELIVERY MODE

11/18/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

## Office Action Summary

**Application No.**

10/575,905

**Applicant(s)**

HATTORI ET AL.

**Examiner**

ILIA OUSPENSKI

**Art Unit**

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20,22-36 and 38 is/are pending in the application.
- 4a) Of the above claim(s) 23-36 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 and 22 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

1. Applicant's preliminary amendment and remarks filed on 09/25/2009 are acknowledged.

Claims 21 and 37 have been canceled.

Claims 1 – 20, 22 – 36 and 38 are pending.

2. Applicant's amendment to claims 20 and 22 has necessitated a modified restriction requirement to include these claims, as set forth below.

3. Applicant's election with traverse of Group II and the Species of SEQ ID NOS: 1 and 2 is acknowledged. Applicant's grounds for traversal are addressed in section 5 below.

Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement between Groups I – X (claims 1 – 19) and Groups XI – XIX (claims 23 – 28), Applicant has not traversed the restriction requirement between Groups I – X and Groups XI – XIX (MPEP § 818.03(a)). Therefore, claims 23 – 28, and claims 29 – 36 and 38 dependent therefrom are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being drawn to nonelected inventions.

Claims 1 – 20 and 22 are presently under consideration.

***Restriction Requirement***

4. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

I. Claims 1 – 19 and 22, drawn to a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 7 and 8, and to compositions and kits comprising said antibody.

II. Claims 1 – 19 and 22, drawn to a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 9 and 10, and to compositions and kits comprising said antibody.

III. Claims 1 – 19 and 22, drawn to a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 19 and 20, and to compositions and kits comprising said antibody.

IV. Claims 1 – 19 and 22, drawn to a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 13 and 14, and to compositions and kits comprising said antibody.

V. Claims 1 – 19 and 22, drawn to a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 23 and 24, and to compositions and kits comprising said antibody.

VI. Claims 1 – 19 and 22, drawn to a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 5 and 6, and to compositions and kits comprising said antibody.

VII. Claims 1 – 19 and 22, drawn to a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 17 and 18, and to compositions and kits comprising said antibody.

VIII. Claims 1 – 19 and 22, drawn to a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 15 and 16, and to compositions and kits comprising said antibody.

IX. Claims 1 – 19 and 22, drawn to a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 21 and 22, and to compositions and kits comprising said antibody.

X. Claims 1 – 19 and 22, drawn to a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 11 and 12, and to compositions and kits comprising said antibody.

XI. Claim 20, drawn to a method for preventing and/or treating a viral disease comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in

particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 7 and 8, and to compositions and kits comprising said antibody.

XII. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a viral disease comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 9 and 10, and to compositions and kits comprising said antibody.

XIII. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a viral disease comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 19 and 20, and to compositions and kits comprising said antibody.

XIV. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a viral disease comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 13 and 14, and to compositions and kits comprising said antibody.

XV. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a viral disease comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 23 and 24, and to compositions and kits comprising said antibody.

XVI. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a viral disease comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor,

in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 5 and 6, and to compositions and kits comprising said antibody.

XVII. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a viral disease comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 17 and 18, and to compositions and kits comprising said antibody.

XVIII. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a viral disease comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 15 and 16, and to compositions and kits comprising said antibody.

XIX. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a viral disease comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 21 and 22, and to compositions and kits comprising said antibody.

XX. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a viral disease comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 11 and 12, and to compositions and kits comprising said antibody.

XXI. Claim 20, drawn to a method for preventing and/or treating a malignant neoplasm comprising the step of administering a bispecific antibody that has an activity

of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 7 and 8, and to compositions and kits comprising said antibody.

XXII. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a malignant neoplasm comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 9 and 10, and to compositions and kits comprising said antibody.

XXIII. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a malignant neoplasm comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 19 and 20, and to compositions and kits comprising said antibody.

XXIV. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a malignant neoplasm comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 13 and 14, and to compositions and kits comprising said antibody.

XXV. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a malignant neoplasm comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 23 and 24, and to compositions and kits comprising said antibody.

XXVI. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a malignant neoplasm comprising the step of administering a bispecific antibody that has

an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 5 and 6, and to compositions and kits comprising said antibody.

XXVII. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a malignant neoplasm comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 17 and 18, and to compositions and kits comprising said antibody.

XXVIII. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a malignant neoplasm comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 15 and 16, and to compositions and kits comprising said antibody.

XXIX. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a malignant neoplasm comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 21 and 22, and to compositions and kits comprising said antibody.

XXX. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a malignant neoplasm comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 11 and 12, and to compositions and kits comprising said antibody.

XXXI. Claim 20, drawn to a method for preventing and/or treating an immune disease comprising the step of administering a bispecific antibody that has an activity of

functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 7 and 8, and to compositions and kits comprising said antibody.

XXXII. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a immune disease comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 9 and 10, and to compositions and kits comprising said antibody.

XXXIII. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a immune disease comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 19 and 20, and to compositions and kits comprising said antibody.

XXXIV. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a immune disease comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 13 and 14, and to compositions and kits comprising said antibody.

XXXV. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a immune disease comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 23 and 24, and to compositions and kits comprising said antibody.

XXXVI. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a immune disease comprising the step of administering a bispecific antibody that has an

activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 5 and 6, and to compositions and kits comprising said antibody.

XXXVII. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a immune disease comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 17 and 18, and to compositions and kits comprising said antibody.

XXXVIII. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a immune disease comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 15 and 16, and to compositions and kits comprising said antibody.

XXXIX. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a immune disease comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 21 and 22, and to compositions and kits comprising said antibody.

XXXX. Claims 1 – 19 and 22, drawn to a method for preventing and/or treating a immune disease comprising the step of administering a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor, in particular an antibody comprising an anti-AR2 chain comprising SEQ ID NOS: 11 and 12, and to compositions and kits comprising said antibody.

In accordance with 37 CFR 1.499, Applicant is required, in response to this action, to elect a single invention to which the claims must be restricted. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. The inventions listed as Groups I – XXXX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions of Groups I – XXXX are deemed to have no special technical feature that defines the contribution over the prior art of Ledbetter et al. (US Patent No. 6,010,902; of record). Ledbetter et al. teach bispecific antibodies which bind to the CD3 component of the T cell receptor and induce proliferation of T cells (e.g. Example 6). As one of skill in the art is aware, the T cell receptor is a heteromolecule-comprising receptor mediating the proliferation of T cells upon binding of a ligand. Therefore, the bispecific antibodies taught by Ledbetter et al. functionally substitute for the ligand of the T cell receptor and as such, the teachings of Ledbetter et al. anticipate at least the instant claim 2.

Applicant alleges at page 12 of the Remarks that even if claim 2 is anticipated, there is a special technical feature among one or more of the inventions set forth as Groups I – X.

In response, the technical feature common to Inventions defined herein as Groups I – XXXX is a bispecific antibody that has an activity of functionally substituting for a ligand of a heteromolecule-comprising receptor. This technical feature is anticipated by the teachings of Ledbetter et al., as addressed above. Therefore, the

inventions of Groups I – XXXX do not have a special technical feature when viewed over the teachings of the prior art.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art, they do not have a single general inventive concept and so lack unity of invention.

### ***Species Election***

5. The species election requirement set forth in the previous Office Action is reiterated in the interest of completing the record. Applicant's election of Species A as set forth below is acknowledged.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicant is required to elect a species wherein the anti-AR1 chain comprises:

- A. SEQ ID NOS: 1 and 2; or
- B. SEQ ID NOS: 3 and 4.

These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features, for the same reasons as set forth in section 5 supra.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is (571)272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ILIA OUSPENSKI/  
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November 13, 2009